

From data availability to data usability:

Operationalising RBQM with analysis ready datasets

Abstract



Many organisations have adopted **Risk-Based Quality Management (RBQM)** but continue to struggle with generating consistent and trusted risk signals across studies. This challenge often manifests operationally as delayed decision-making and heavy manual effort by RBQM teams.



A key limitation lies not in the availability of analytics tools, but in the gap between **data availability and data usability**. Early RBQM implementations often rely on study-specific data preparation approaches and manually maintained workflows that are difficult to validate, standardise, and scale.



This session explores how establishing **Analysis-Ready Datasets (ARDs)** as a governed operational capability can enable more sustainable RBQM aligned with Quality by Design principles. It emphasises the critical role of business-led development in defining what “analysis-ready” means in practice, including readiness criteria.

It shares practical lessons in harmonising heterogeneous clinical data sources, standardising transformation frameworks, and embedding fit-for-purpose validation practices that support reliable central monitoring across study portfolios.

The discussion also considers how modern data platforms such as Databricks can support the transition from making data available to making it usable by enabling traceable and standardised data workflows. Strengthening data usability in this way helps reduce variability in risk signal generation and supports more consistent risk-driven oversight.

Particular emphasis is placed on redefining ownership of data readiness, positioning ARDs as long-lived operational assets rather than study-level deliverables. By shifting accountability for ARDs from ad-hoc technical build activities to business-led, product-oriented capabilities, organisations can support more proactive oversight. This approach also lays the groundwork for emerging Risk-Based Data Management practices.

Attendees will gain practical insights into designing and sustaining ARDs as a foundational capability for enterprise-scale RBQM.

3 Key lessons for the audience



RBQM programmes stall when data is available but not consistently usable.

Reliable risk signals depend less on analytics sophistication and more on how data is prepared, structured, and maintained across studies.



Scaling RBQM requires moving from study-level solutions to shared data workflows.

Standardising how data is integrated and prepared enables consistent risk oversight and reduces duplication across studies.



Long-term RBQM success is shaped by early decisions on data, validation, and architecture.

These foundations determine how effectively organisations can scale risk oversight and enable automation and AI-driven capabilities over time.

Who is this session relevant for?

The topic touches on data engineering and platform capabilities and is presented through a business and operational lens rather than a technical one. The session is fundamentally about a common problem many RBQM programmes face: data is available, but not reliably usable.

The concepts - ownership of data readiness, moving from study-level workarounds to shared, governed workflows, and building durable operational capabilities are accessible and relevant to anyone involved in RBQM oversight, regardless of their technical background.

The session will draw from practical examples and avoid implementation-level detail, ensuring the session resonates with clinical operations, quality, and programme leadership audiences as much as with technical practitioners.